

15 November 2012
EMA/CHMP/669278/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Bexsero

Meningococcal group B Vaccine (rDNA, component, adsorbed)

On 15 November 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bexsero, suspension for injection intended for the prophylaxis against invasive disease caused by *N. meningitidis* group B strains. The applicant for this medicinal product is Novartis Vaccines and Diagnostics S.r.l. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Bexsero is a Meningococcal group B Vaccine (rDNA, component, adsorbed), Meningococcal vaccines (ATC Code: J07AH09) which stimulates the production of bactericidal antibodies against vaccine antigens (NHBA, NadA, fHbp and PorA P1.4).

The benefits with Bexsero are its ability to protect against invasive group B meningococcal disease. The most common side effects are fever, sleepiness, diarrhoea, vomiting, rash, injection site pain, myalgia and arthralgia. A pharmacovigilance plan for Bexsero will be implemented as part of the marketing authorisation.

The approved indication is: "Bexsero is indicated for active immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by *Neisseria meningitidis* group B. The impact of invasive disease in different age groups as well as the variability of antigen epidemiology for group B strains in different geographical areas should be considered when vaccinating. See section 5.1 of SmPC for information on protection against specific group B strains. The use of this vaccine should be in accordance with official recommendations." It is proposed that Bexsero be prescribed by physicians experienced in the disease caused by *Neisseria meningitidis* group B.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Bexsero and therefore recommends the granting of the marketing authorisation.